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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,514	02/11/2004	Kerry Zang	073275.0163	5263
5073	7590	12/01/2006	EXAMINER	
BAKER BOTTS L.L.P. 2001 ROSS AVENUE SUITE 600 DALLAS, TX 75201-2980			MILLER, CHERYL L	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/777,514		ZANG ET AL.	
	Examiner		Art Unit	
	Cheryl Miller		3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-17, 19-33 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 12-17, 19-23, 27-33, and 36-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 9, 2006 and October 30, 2006 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-8, 12-23, and 27-33 have been considered but are moot in view of the new ground(s) of rejection.

Response to Amendment

The declaration filed on October 9, 2006 under 37 CFR 1.131 has been considered but is ineffective to overcome the Lepow et al. (US 2005/0177243 A1) reference. The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Lepow reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). The mere admission that a claim was conceived before the date is insufficient evidence.

The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Lepow reference. The mere admission that a claim was actually reduced to practice before the Lepow effective date is insufficient evidence. No proof has been provided that the claimed invention was made or conceived, or sold before the date of the Lepow reference. The declaration is thus ineffective and the Lepow rejection is still applicable.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-8, 12-17, 19-23, 27-33, and 36-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The following recitations were not found in the specification or drawings.

Referring to claims 1 and 17:

Referring to claim 1, "a body including a conical portion" is recited. The embodiment of figures 1a-1c show the body external surface 30 (root) to seemingly be parallel to the longitudinal axis (not conical). Each root portion between the threads seems to be straight rather than angled/conical as claimed. Although figure 2 is shown to be conical, this is before the threads are carved *into* the body, thus leaving a tapered external thread surface, but not

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necessarily a tapered/angled root body surface. Therefore, as maybe the external thread surface is shown to be tapered/conical (by angle 44), there was no support found for the body/root portion to be conical as well. The root body shape may be considered *generally* conical at best. Claims 3-8, 12-16, 32, 36, and 37 depend upon claim 1 and inherit all problems associated with the claim.

Referring to claims 1 and 17, "a plurality of uninterrupted threads" is recited. Although applicant may have support for a plurality of threads, and also have support for an uninterrupted thread, the applicant does not have support for a plurality of uninterrupted threads. Only *one* continuous thread is shown in the figures 1a-1c. Claims 3-8, 12-16, 19-23, 27-33, and 36-39 depend upon claims 1 and 17 and inherit all problems associated with the claims.

Referring to claims 3 and 4, the applicant has claimed the conical portion of the body (root) to have a specific taper angle. This is not supported by the specification. The specification discloses taper angle 44, however according to the drawings, the taper angle is referring to the exterior thread angle or taper angle of the entire implant body (not the conical body interior to the threads).

Referring to claims 32-33, constant thread height was not found in the specification or in figures 1a-1c. In the figures, the thread seemingly tapers in height.

Referring to claims 37 and 39, equal taper angles of the crests and root body was not found by the examiner to be in the specification. It is requested that the applicant point out exactly where in the specification support for all above such subject matter is located.

Otherwise, the subject matter is being treated as new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 5, 17, 19, 20, 21, and 36-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Lepow et al. (US 2005/0177243 A1, previously cited). Lepow discloses an implant (12) comprising a body having a conical portion (core exterior 28 is conical), a plurality of uninterrupted threads (34) formed on an exterior surface of the conical portion (see figs), the threads having a crest with a substantially flat surface (see figs) and the crests defining a cone having a degree of taper (50) the same as the conical body (43; both disclosed to be between 0-30 degrees, which includes 18 degrees; P0039). Lepow's implant is capable of being placed in the sinus tarsi joint (fig.2). Lepow discloses an engagement (bore 22) on the implant for a tool. Lepow discloses the threads to be tapered (see figs).

Claims 1, 3-5, 17, 19-21, 36, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Simon et al. (US 5,951,560, cited previously). Simon discloses an implant (10, 30, 80) comprising a body (B in figs.1-9 OR alternatively, root in figs.15-22) having a conical portion (entire length of B in figs.1-9 OR alternatively, FS portions in figs.15-22). Simon discloses the taper angles claimed (figs.1-9, body B tapers at an angle of 11 degrees and figs.15-

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22, FS portion tapers at an angle of 30 degrees and MS tapers at an angle of 17-26 degrees; col.4, lines 26-45; col.6, lines 41-65; col.7, lines 1-4) conical portion may be considered), a plurality of uninterrupted threads (14, 34, 84) formed on an exterior surface of the conical portion (see figs), the threads having a crest with a substantially flat surface (see figs) and the threads being tapered with respect to the longitudinal axis. Simon's implant is *capable* of being placed in the sinus tarsi joint. Simon discloses an engagement (22) on the implant for a tool. Simon discloses the threads to be tapered (see figs).

Claims 1, 17, 36, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Huebner (US 5,964,768). Huebner discloses an implant (410; fig.19 for example) comprising a body (412) having a conical portion (seen in fig.1a), a plurality of uninterrupted threads (418) formed on an exterior surface of the conical portion (see figs), the threads having a crest with a substantially flat surface (see figs 19-21) and the threads being tapered with respect to the longitudinal axis. Huebner's implant is *capable* of being placed in the sinus tarsi joint.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-8, 12-16, 22, 23, and 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lepow et al. US 2005/0177243 A1, previously cited). Lepow discloses an implant sized and configured to fit in the sinus tarsi location of the subtalar joint substantially as

claimed. Lepow discloses a conical body with flat threads (see above) the threads having a taper angle, height, width, and pitch as seen in the figures. Lepow however, is silent to mention any *specific dimensions* of the threads. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the thread dimensions claimed, since where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 6-8, 12-16, 22, 23, and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon et al. (US 5,951,560, cited previously). Simon discloses an implant sized and configured to fit in the sinus tarsi location of the subtalar joint substantially as claimed. Simon discloses a conical body with flat threads (see above) the threads having a taper angle, height, width, and pitch as seen in the figures. Simon however, does not disclose the exact dimensions claimed with respect to the threads. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the thread dimensions claimed, since where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 3-8, 12-16, 19-23, and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebner (US 5,964,768). Huebner discloses an implant sized and configured to fit in the sinus tarsi location of the subtalar joint substantially as claimed (see above).

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Huebner discloses a conical body with flat threads (see above) the threads having a taper angle, height, width, and pitch as seen in the figures. Huebner however, does not disclose the exact dimensions claimed with respect to the threads. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the thread dimensions claimed, since where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

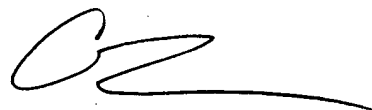
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cheryl Miller



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